MAR 16 2012 K113474 p1/3

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NeoCoil

5. Revised 510(k) Summary

5.1. Applicant

NeoCoil, LLC
N27 W23910A Paul Rd
Pewaukee, WI 53072

5.2. Contact

Steven Nichols
Chief Operating Officer
262-347-1250 (office)
261-347-1251 (fax)
steve.nichols@neocoil.com

5.3. Preparation Date

11/11/2011

5.4. Name of Device

- Proprietary Name: 1.5T GEM Flex Coil
- Common Name: Magnetic Resonance Specialty Coil
- Classification: 21 CFR 892.1000, Product Code MOS

5.5. Model Numbers

- NC021000 GEM Flex Coil, 1.5T
- NC030000 GEM Flex Coil 16-L Array, 1.5T Receive Only
- NC023000 GEM Flex Coil 16-M Array, 1.5T Receive Only
- NC024000 GEM Flex Coil 16-S Array, 1.5T Receive Only
- NC02200x GEM Flex Interface 8ch Combined, 1.5T HD-Connector
  GEM Flex Interface 16ch Fixed, 1.5T P-Connector
  GEM Flex Interface 16ch Fixed, 1.5T HD-Connector

5.6. Device Description

The NeoCoil 1.5T GEM Flex Coil is a receive-only phased array coil system for imaging the upper and lower extremities, chest, abdomen, pelvis, head, neck, and spine in pediatric and adult populations. This system consists of:

- Three formable, flexible and detachable antennae of different size that can be wrapped or orientated flat, in order to accommodate various anatomic shapes and sizes.
- A multichannel low-noise coil interface matched to the MRI scanner for compatibility with 8 or 16 channel systems.
- Multi-purpose accessory immobilization devices designed for patient comfort and reduced motion artifacts.

The NeoCoil 1.5T GEM Flex Coil is tuned to receive RF frequency corresponding to the proton precession in a 1.5 tesla magnetic field, which is governed by the Larmor equation.

5.7. Predicate Device

- 1.5T MetaFlexCoil (K101632)

5.8. Comparison to Predicate

The NeoCoil 1.5T GEM Flex Coil is identical in physical, performance, design and material characteristics to the legally marketed device, the 1.5T MetaFlexCoil, K101632, as cleared on 08/24/2010.

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The differences introduced in this submission include:

- Updated Indications for Use that includes pediatric populations, as well as imaging applications in the chest, abdomen and pelvis.
- Updated labeling that includes coil setup and positioning that support the expanded Indications for Use.

The Indications for Use have been expanded to be consistent with the capabilities of the 1.5T MetaFlexCoil.

Clinical testing demonstrates that the differences in the expanded Indications for Use do not affect the safety and effectiveness of the device when used as labeled.

5.9. Indications for Use

To be used in conjunction with a GE 1.5 HD or DV Series Magnetic Resonance Scanner to produce diagnostic images of the upper and lower extremities, chest, abdomen, pelvis, head, neck, and spine in pediatric and adult populations that can be interpreted by a trained physician.

5.10. Intended Use

Intended use of the 1.5T GEM Flex Coil is identical to that of routine MR imaging; specifically to produce diagnostic images of the upper and lower extremities, chest, abdomen, pelvis, head, neck, and spine in pediatric and adult populations.

Use of the device in conjunction with a MRI scanner is unchanged; the anatomic applications have been expanded to be consistent with the capabilities of the 1.5T MetaFlexCoil.

5.11. Testing

The following data has been submitted, referenced or relied on to demonstrate that the 1.5T GEM Flex Coil is safe and effective given its expanded Indications for Use. The device's performance meets the requirements of pre-defined acceptance criteria and intended uses.

Performance testing - Bench:

Test	Pass/Fail Criteria	Result
Max B1 in first fault conditions	pre-defined performance standards	**Pass:** coil does not arc or show any signs of voltage breakdown
Surface Temperature in normal and first fault conditions	pre-defined performance standards	**Pass:** RF heating is not greater than 39^{o} C in normal or first fault conditions
NEMA MS 6-2008	pre-defined performance standards	**Pass:** Expanded indications do not change acceptance criteria initially established for the 1.5T MetaFlexCoil (K101632); SNR and Uniformity are consistent with the requirements for indications for use.

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Published Standards testing:

Standard	Purpose
IEC 60601-1	Electromechanical safety
IEC 60601-2-33	Electromechanical safety
ISO 10993-1	Biocompatibility
60601-1-2	ESD

Performance testing - Clinical:
Clinical data submitted exhibits a mix of scanner configurations, pulse sequences, imaging options, field of view and anatomy in the axial, sagittal and coronal planes as recommended in the FDA guidance, *Guidance for the Submission Of Premarket Notifications for Magnetic Resonance Diagnostic Devices.*

Clinical performance testing includes imaging from the pediatric subpopulations specified in Table 1 of the FDA guidance, *Premarket Assessment of Pediatric Medical Devices.*

No adverse events were reported during clinical performance testing; the 1.5T GEM Flex Coil system demonstrated performance adequate to support the expanded Indications for Use.

5.12. Conclusion
This submission demonstrates that the expanded Indications for Use associated with pediatric, chest, abdominal and pelvic applications are as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Steven Nichols
Chief Operating Officer
NeoCoil, LLC
N27 W23910-A Paul Road
PEWAUKEE WI 53072

MAR 16 2012

Re: K113474
Trade/Device Name: 1.5T GEM Flex Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: February 28, 2012
Received: February 29, 2012

Dear Mr. Nichols:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

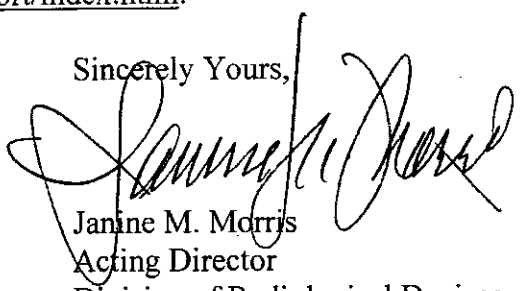
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,



Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K113474

Indications for Use

510(k) Number (if known): _____

Device Name: 1.5T GEM Flex Coil

Indications for Use:

To be used in conjunction with a GE 1.5 HD or DV Series Magnetic Resonance Scanner to produce diagnostic images of the upper and lower extremities, chest, abdomen, pelvis, head, neck, and spine in pediatric and adult populations that can be interpreted by a trained physician.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K113474